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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,670	07/21/2003	Yuanhao Li	CELL-024	1674

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EXAMINER

CHEN, SHIN LIN

ART UNIT PAPER NUMBER

1632

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/624,670	LI ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 and 11-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of group II, claims 7-9 and 11-21, and SEQ ID No. 1 in the reply filed on 7-24-06 is acknowledged. The traversal is on the ground(s) that SEQ ID No. 1 is a subset of the 1 kb sequence of SEQ ID No. 2, therefore, there is no undo burden on the examiner to search and examine the full set of claims. There is no evidence that combination (group II) is patentable without the details of the subcombination (group I). This is not found persuasive because SEQ ID No. 1 and 2 represent two different nucleotide sequences. Both of them are different regulatory sequences and have different regulatory activities, therefore, they are patentably distinct from each other. A search for SEQ ID No. 1 does not require a search for SEQ ID No. 2. Further, the TRE could be used to control expression of other non-adenoviral genes and the replication-competent adenovirus vector of group II can be used to infect a host cell while the TRE of group I cannot be used as such.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-6 and 10, and SEQ ID No. 2, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7-24-06.

Applicants' amendment filed on 7-24-06 has been entered. Claims 7 and 8 have been canceled. Claims 9, 11-15, 17 and 19-21 have been amended. Claims 1-6 and 9-21 are pending. Claims 9 and 11-21 are considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 9 and 11-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase “PRL-3 TRE” in claim 9 is vague and renders the claim indefinite. The phrase “PRL-3 TRE” is an abbreviation that can stand for various meanings. It is unclear what meaning is intended in the claim. Spelling out the phrase “PRL-3 TRE” would be remedial. Claims 11-21 depend from claim 9 but fail to clarify the indefiniteness.

The term “IRES” in claim 16 is vague and renders the claim indefinite. The phrase “IRES” is an abbreviation that can stand for various meanings. It is unclear what meaning is intended in the claim. Spelling out the phrase “IRES” would be remedial.

The term “derived from” in claim 9 is vague and renders the claim indefinite. The term “derived from” can mean any kind of modification. It is unclear as to the metes and bounds of what would be considered “derived from”. The specification fails to specifically define the term “derived from”. Claims 11-21 depend from claim 9 but fail to clarify the indefiniteness.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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6. Claims 9 and 11-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a PRL-3 TRE sequence comprising the sequence of SEQ ID No. 1, does not reasonably provide enablement for the use of various PRL-3 TRE sequence derived from the sequence of SEQ ID No. 1 and a composition comprising the replication-competent adenovirus vector as claimed for pharmaceutical use. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are drawn to a replication-competent adenovirus vector comprising an adenovirus gene essential for replication under the control of a PRL-3 TRE derived from the 0.6kb sequence of SEQ ID No. 1, a composition comprising said replication-competent adenovirus vector, and an isolated host cell comprising said adenovirus vector. Claims 15 and 16 specify the adenoviral vector comprises first and second adenoviral genes co-transcribed under the control of said PRL-TRE, and the second gene is under the control of an IRES. Claim 17 specifies the adenoviral gene essential for replication is E1A or E1B. Claim 18 specifies E1A or W1B has a mutation in or deletion of its endogenous promoter. Claim 19 specifies E1B has a deletion of the 19-kDa region.

Claim 20 is drawn to a composition comprising an adenovirus vector and a pharmaceutically acceptable excipient, which implies therapeutic effect in vivo. Thus, claim 20 remains rejected for the reasons set forth in the preceding Official action mailed 4-24-06.

The claims are drawn to a replication-competent adenovirus vector comprising an adenovirus gene essential for replication under the control of a PRL-3 TRE derived from the 0.6kb sequence of SEQ ID No. 1. The specification fails to specifically define the term "derived

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from”, and the term “derived from” encompasses various modification, including addition, deletion, substitution, chemical modification and physical modification etc. Therefore, the claims encompass using a TRE that differs dramatically from the 0.6kb nucleotide sequence of the human TRE region. The structural feature that contributes to the TRE activity has not been disclosed. The specification only discloses the nucleotide sequences of SEQ ID No. 1 and 2, but there is no structure-function analysis of the disclosed TREs to provide guidance on the essential nucleotides or structure of the molecule that could be modified and still retains function. There is no teachings in the prior art regarding the elements that are responsible for the specific activity of a TRE that would provide guidance on which fragments of the polynucleotide shown in SEQ ID No. 1 or what kind of modification would still retain activity. Absent specific guidance, one skilled in the art at the time of the invention would not know what kind of activity would be for those various TREs derived from SEQ ID No. 1, and would not know how to use those TREs derived from SEQ ID No. 1. Thus, one skilled in the art at the time of the invention would require undue experimentation to practice over the full scope of the invention claimed.

For the reasons discussed above, it would have required undue experimentation for one skilled in the art at the time of the invention to practice over the full scope of the invention claimed. This is particularly true given the nature of the invention, the state of the prior art, the breadth of the claims, the amount of experimentation necessary, the working examples provided and scarcity of guidance in the specification, the level of skilled artisan which is high, and the unpredictable nature of the art.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.



**SHIN-LIN CHEN
PRIMARY EXAMINER**